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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,384	01/30/2006	Brian Frostrup	2815-0347PUS1	5532

2292 7590 07/10/2008  
BIRCH STEWART KOLASCH & BIRCH  
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EXAMINER
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RODRIGUEZ-GARCIA, VALERIE

ART UNIT	PAPER NUMBER
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4161

NOTIFICATION DATE	DELIVERY MODE
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07/10/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,384	<b>Applicant(s)</b> FROSTRUP ET AL.	
	<b>Examiner</b> VALERIE RODRIGUEZ-GARCIA	<b>Art Unit</b> 4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 19 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/30/06</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 13-23 are currently pending. Claims 1-12 have been canceled by the Applicant

Applicant's election of Group I, claims 13-15 and 20 drawn to the salt (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane L-tartrate monohydrate, in the reply filed on 06/19/08 is acknowledged. In response to applicant's election, Groups II-X and the claims included therein have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Election was made **without** traverse in the reply filed on 06/19/08.

Claims 13-15 and 20 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

### ***Priority***

This application is a 371 of PCT/EP04/51651 filed on 07/29/2004, which claims priority benefit of provisional application 60/494090 filed on 08/12/2003 and of foreign application DENMARK PA 2003 01117 filed on 07/31/2003. The earliest effective U.S. filing date is 08/12/2003, the filing date of the provisional application 60/494090.

### ***Objections***

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

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The **abstract** should be in narrative form and **generally limited to a single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case the **abstract is two paragraphs**.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 13-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheel-Kruger *et al.* (US 6,288,079B1) as evidenced by Berge *et al.* (J. Pharm. Sci. 1977; 66(1);1-19)

The instant claims are drawn to a salt of (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane tartrate, octane L-tartrate, octane L-tartrate monohydrate and a pharmaceutical composition comprising the salt of (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane tartrate.

Scheel-Kruger *et al.* disclose the salt (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane citrate (column 22, lines 5-40, example 15). It disclose pharmaceutically acceptable addition salts including the tartrate salt as salts formed by procedures well know in the art (column 5, lines 24-30). Scheel-Kruger *et al.* further specify that these compounds may exist unsolvated (meaning anhydrous) as well as in solvated forms (monohydrate, polyhydrate) (column 6, lines 11-15), and as isomers and mixtures (column 6, lines 16-20). Pharmaceutical formulations comprising pharmaceutically acceptable salts or derivatives with acceptable carriers is also mentioned (column 10, lines 45-53). The tartrate salts are the 4<sup>th</sup> most commonly commercially marketed salts (page 2, Table 1). Organic salts of basic drugs, such as tartrate salts, are more soluble in water than inorganic salts. Furthermore, dicarboxylate salts with small alkyl groups where the alkyl group is hydroxylated increases solubility of

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the drug (page 8, 1<sup>st</sup> column, 1<sup>st</sup> and 2<sup>nd</sup> paragraph). Tartrate salts are such examples, and it would be desirable to make pharmaceutically acceptable salts of these.

Also see *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007). cf. *In re Aller*, 220 F.2d 454 (CCPA 1955). "It is a matter of routine optimization for a person of skill in the art to determine the best pharmaceutically acceptable salt from those salts known to be useful in pharmaceutical active agents."

As such, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to make the salt (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane tartrate, the L-isomer of such octane tartrate salt, the monohydrate of such octane L-tartrate salt and a pharmaceutical composition comprising a therapeutically effective amount of a salt of (1R, 2R, 3S, 5S)-2-methoxymethyl-3-(3,4-dichlorophenyl)-8-azabicyclo[3.2.1]octane tartrate, as per the teachings of Scheel-Kruger *et al.* Claims 13-15 and 20 are thus rejected.

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VRG

/Ashwin Mehta/  
Primary Examiner, Technology Center 1600